PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION OF	)	
Moriarty, R.M.; Penmasta, R.;	)	
Guo, L.; Rao, M.S.;	)	
and Mehta, R.G.	)	
	)	Group No. 1616
SERIAL NO.: 09/008,957	)	
	)	
FILED: Jan. 20, 1998	)	Examiner: Badio
	)	
TITLE: 1α-HYDROXYVITAMIN D5,	)	
ITS SYNTHESIS AND USE	)	
IN CANCER PREVENTION	)	
AND THERAPY	)	

DECLARATION UNDER 37 CFR § 1.132

I, Samad Hedayat, declare as follows:

1.   I am a citizen of the United States of America residing at 1037 Bellefort Ave, Oak Park, IL 60302.

2.   I am a graduate of Cornell University, having received a Ph.D. in Statistics in 1969. I am currently employed by the University of Illinois at Chicago in the position of Professor of Mathematics and Statistics. I am on the editorial boards of several international statistical journals, including J. of American Statistical Association (USA), J. of Statistical Planning and Interference (The Netherlands), and Data and Statistics (Switzerland.

3.   I have preformed statistical analyses of the data in the attached table from the Declaration under 37 CFR 1.132 of Dr. Robert Moriarty, dated December 5, 1999 and attached hereto. The required summary statistics needed for the statistical analyses performed are also included in the attached table.

4. I compared the mean serum calcium (mg/100ml) of the following three compounds under variance heteroscedicity: $1\alpha(OH)D_5$, $1\alpha(OH)D_4$ and $1,\alpha,25(OH)_2D_3$. In making two sided pairwise comparisons I adjusted (decreased) the degrees of freedom associated with the student's t-tests to accommodate for the apparent lack of homogeneity in the variances. The statistical results in the form of p-values are summarized in the table and further explained below.

5. At the two lowest dose levels (0.042 and 0.25 µg/kg/day), the mean serum calcium (mg/100ml) of $1,\alpha(OH)D_5$ is significantly less than the mean serum calcium (mg/100ml) of $1\alpha(OH)D_4$.

6. At a dose level of 1.50 µg/kg/day the mean serum calcium (mg/100ml) of $1,\alpha(OH)D_5$ is less than the mean serum calcium (mg/100ml) of $1\alpha(OH)D_4$. However, the corresponding two-sided p-value for this statistical detection is about 0.1.

7. At the two lowest dose levels (0.042 and 0.25 µg/kg/day), the mean serum calcium (mg/100ml) of $1,\alpha(OH)D_5$ is significantly less than the mean serum calcium (mg/100ml) of $1\alpha,25(OH)_2D_3$.

8. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the

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validity of any patent that may issue from the above-identified

U.S. patent application.

Sam Hedayat

Samad Hedayat, Ph.D.

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Date

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Effects of Vitamin D Analogs on Serum Calcium in Vitamin D-Deficient Rats

Compound	Number of rats	Dose (µg/kg/day)	Mean Serum Calcium (mg/100ml) ±S.D.	p-value (2-sided test)
$1\alpha,25(OH)_2D_3$	8	0.042	8.1 ± 1.15	0.00089
$1\alpha(OH)D_5$	8	0.042	6.0 ± 0.63	
$1\alpha(OH)D_4$	8	0.042	7.1 ± 0.80	0.00902
$1\alpha(OH)D_5$	8	0.042	6.0 ± 0.63	
$1\alpha,25(OH)_2D_3$	10	0.25	10.1 ± 1.84	0.01223
$1\alpha(OH)D_5$	10	0.25	7.9 ± 1.5	
$1\alpha(OH)D_4$	7	0.25	11.8 ± 0.45	0.00001
$1\alpha(OH)D_5$	10	0.25	7.9 ± 1.5	
$1\alpha(OH)D_4$	9	1.5	12.7 ± 0.37	0.0891
$1\alpha(OH)D_5$	10	1.5	12.2 ± 0.8	

Note: p-values are for two-sided student t-test using Satterthwaite's approximation for unequal variance cases.